Exhibit

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- VOLUME D -
IN THE UNITED STATES DISTRICT COURT
IN AND FOR THE DISTRICT OF DELAWARE

CORDIS CORPORATION, : CIVIL ACTION
Plaintiff :
:
vs. :
:
MEDTRONIC AVE, INC., BOSTON :
SCIENTIFIC CORPORATION and :
SCIMED LIFE SYSTEMS, INC., :
Defendants : NO. 97-550 (SLR)

BOSTON SCIENTIFIC CORPORATION : CIVIL ACTION
and SCIMED LIFE SYSTEMS, INC., :
Plaintiffs :
:
vs. :
:
ETHICON, INC., CORDIS CORP. :
and JOHNSON & JOHNSON :
INTERVENTIONAL SYSTEMS CO., :
Defendants : NO. 98-19 (SLR)

CORDIS CORPORATION, : CIVIL ACTION
Plaintiff :
:
vs. :
:
MEDTRONIC AVE, INC., BOSTON :
SCIENTIFIC CORPORATION and :
SCIMED LIFE SYSTEMS, INC., :
Defendants : NO. 98-197 (SLR)

Wilmington, Delaware
Tuesday, March 22, 2005
9:20 o'clock, a.m.

BEFORE: HONORABLE SUE L. ROBINSON, Chief Judge, and a jury

Valerie J. Gunning and
Leonard A. Dibbs,
Official Court Reporters

APPEARANCES:

ASHBY & GEDDES
BY: STEVEN J. BALICK, ESQ.

-and-

PATTERSON, BELKNAP, WEBB & TYLER LLP
BY: GREGORY L. DISKANT, ESQ.,
EUGENE M. GELERNTER, ESQ.,
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(New York, New York)

-and-

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YOUNG, CONAWAY, STARGATT & TAYLOR
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-and-

KENYON & KENYON
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(New York, New York)

Counsel for Boston Scientific
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- - -

PROCEEDINGS

(Proceedings commenced at 9:20 a.m., and the following occurred without the presence of the jury.)

MR. DISKANT: Good morning, your Honor.

THE COURT: Good morning.

MR. DISKANT: I think we've reached a substantial number of agreements.

First, the parties have agreed on an instruction to request your Honor to give at the beginning of the testimony. I will read it to you. I've written it out as neatly as I can. I hope you can read it. The proposed curative instruction is:

In light of yesterday's testimony, I want to instruct you that there is only one infringement issue for you to decide in this case. That is the question whether the NIR stent meets the substantially uniform thickness limitation of Claim 23 of the '762 patent.

We've then agreed that Mr. Cavanaugh will ask just one question on the subject of Dr. Richter, and that question will be, in substance:

Dr. Richter, you understand that the only infringement issue in this case is whether the NIR stent

meets the substantially uniform thickness limitation of Claim 23.

He will just say yes. He will just say yes. And we will then abandon the limitations analysis. We will just start asking him questions about the substantially uniform thickness limitation. If that's acceptable to your Honor, the parties have agreed on that.

MR. BADENOCH: That is acceptable, your Honor and, of course, we assume Mr. Cavanaugh will ask it in a non-confrontational tone.

MR. CAVANAUGH: All of Mr. Cavanaugh's questions are non-confrontational, your Honor.

MR. DISKANT: He does the best he can.

THE COURT: He does the best he can?

MR. DISKANT: That's where we are.

Secondly, I made a motion yesterday morning with respect to a host of demonstratives which BSC purported to say Claim 13 was cancelled and put in other claims and argue about other claims.

I think we have agreed largely on that subject. There are -- and most of the slides that I object to are gone.

There is a slide they wish to show, the one that has methods. Here it is.

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BY MR. BADENOCH:
Q. And they say here, to aid in fixation and to resist forces tending to pull out the implanted prosthetic device, the Ersek sleeve has outwardly projecting sharp metal edges.
What does that mean?
A. Correct. So they're arguing, without any basis whatsoever, that the narrow sides of a rectangle like the wooden slats behind you, they're arguing that those narrow sides are, for some reason, sharp.
Q. Let's go to Page 18 in the same argument.
They say here, those skilled in the art would not even consider intraluminally delivering the expanded metal sleeve of Ersek through the vasculature of a lumen, since the sharp metal outwardly projecting edges thereon would present a clear risk to the patient.
Is that part of the same argument?
A. Right. So now, again, they're somehow saying that it's sharp, without explaining how it got sharp, and now they are sort of introducing a level of irresponsibility and danger involved with the device.
Q. Let's go to Page 24.
Here they say, the simple medical reality is that no responsible physician would consider delivering an Ersek type device by catheterization. Any attempt to

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deliver an Ersek device by catheterization would result in shredding of the walls of the body passageway.
Can you comment on that?
A. So, again, they are -- they're somehow saying it's sharp without basis, and now they are directly saying, they're kind of accusing irresponsibility and danger associated with these sharp metal edges which, of course, aren't there.
Q. Now, in some of those excerpts, they refer to a declaration from, of Dr. Andros.
Who's Dr. Andros?
A. Dr. Andros was a physician who provided, basically, as I understand it, expert testimony to the Patent Office. He -- he declared to the Patent Office his opinion about this matter.
Q. And I think we have an excerpt from what he said.
He also said here, no responsible physician would consider intraluminally delivering the Ersek expanded metal fixation sleeve by catheterization through the vasculature of a lumen, since the outwardly projecting edges on the outer periphery thereof would present a clear risk to the patient.
Again, we have these words, any attempt to intraluminally deliver the figures Asian sleeve could result in shredding of the walls of the body passageway.

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A. Right. So -- so we have on the one hand in the previous slide, we have what Cordis, as an applicant for a patent, said to the Patent Office, and now in this case, on this slide, we have what their expert said as an expert in medicine to the Patent Office. And you see, I think these are verbatim, the same words. And as I understand it, the examiner presented with what the inventor says can argue back. But as I understand it, what the -- what an expert says to the Patent Office, the examiner, if he has no literature before him to the contrary, simply has to accept it as the way it is.
Q. Was Cordis successful in this argument?
A. Yes.
Q. And did the examiner end up accepting what Andros said?
A. Yes.
Q. Do you think that Cordis' argument in describing Ersek was correct?
A. No, not at all. As I've said, I don't understand where the sharpness comes from, both in terms of the narrow side of a rectangle being sharp. I don't see where that comes from. And, of course, one who understands the mechanics and examines how Ersek would work, you wouldn't want it to be sharp because you'd want it to expand and be taut. You don't want it to cut

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in and damage the structure of the vessel.
- - -
Q. Did Dr. Andros perform any experiment to support what he was saying about his theory?
A. Not that I'm aware of.
Q. Did you perform any experiment to see whether or not that theory was correct?
A. With Dr. Low's assistance, yes.
Q. Can you describe briefly what experiment you did perform?
- - -

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A. What we did at the lab was, at SciMed, was basically follow Dr. Ersek's instructions for making an expandable tube and then we put it on a balloon and used it as a stent in an animal experiment.
Q. Dr. Snyder, would you look at DX-15357 and 15358 in your -- and tell me what those are?
A. 357 is a brochure from a manufacturer of precision high-grade expanded metal.
Q. And 15358?
A. I'm sorry. 357 is -- is the brochure including a sample.
Q. Is that the expanded metal you actually used to make the stents for your experiment?
A. Yes. This is the same.
MR. BADENOCH: Your Honor, I offer 15257 and 15258.
MR. DISKANT: I do not object to the brochure. I do object to the sample. I think it was used for demonstrative purposes and it shouldn't go to the jury.
THE COURT: I agree.
MR. BADENOCH: All right.
BY MR. BADENOCH:
Q. Dr. Snyder, was the expanded metal that you received flattened?

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A. No. This was -- when you buy expanded metal from any of these companies, it's very standard through the industry. It's slit. It's pulled to a certain distance, and then you can buy it just like that, off that slitting machine, or if you want it to be flat, remember, Dr. Ersek said it's desirably not flattened. He liked the not flattened kind. But you can also tell the manufacturer I like it flattened and they simply roll it back down so those twisted edges get pushed back down. And you can buy it either way.
Q. Could you look at Defendants' Exhibit 15010 and 15292?
A. Yes. These are -- these are both pictures, one from a regular camera, and one from electron microscope, showing some pictures of the actual expanded metal that we used.
MR. BADENOCH: Your Honor, I would offer 15010 and 15292. They're photographs.
MR. DISKANT: No objection.
THE COURT: All right. Thank you.
DEPUTY CLERK: So marked.
*** (Defendants' Exhibits 15010 and 15292 were received into evidence.)
BY MR. BADENOCH:
Q. Doctor, could you explain what these photographs

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show?
A. Sure. This is just a plain camera photograph of the expanded metal and you can see the strands. You can see where the slits were and it has been pulled in this direction, expanded into these diamonds. And then here, you see it kind of from the side, sitting on a surface like this, in the electron microscope. This is the gooey tape that you use in an electron microscope.
Then you can see the twisted strands that have been pulled open and you can see this angle.
Now, I explained before that standard expanded metal is about 1.6 times higher if you just order it and don't ask for anything special, it's about 1.6 times higher. Puts it at sort of an angle like this, then the original width of the slits. The material they happened to have available and we got as a sample had been pulled further beyond the standard amount, so the openings were a little bit bigger than what you get if you just didn't specify. And these were a little bit taller, but you can still see the slant here.
Q. Now, just to be clear, are these the narrow projecting edges of --
A. Right. These are the -- you can see it, maybe right here is a good spot, where it's nicely in focus, you can

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see the narrow side of the rectangle and this is the wide side of the rectangle.
Q. And are the narrow edges sharp?
A. No, not at all.
Remember, this is right off the machine, and the way this machine works, it's a die cutter and it's almost like a scissors. It sheers and if you don't ask for a high grade, there might be a tendency to, like when you cut metal with metal shears, there might be a tendency to get a little bit of an edge there, but when we just ordered this and got a sample out of their stock, you don't even see that. You just see this square edge.
Q. Is this medical grade expanded metal?
A. Well, all we did was ask for 316L, so it's material that you would tend to pick for implant, but we didn't ask for traceability, we didn't ask them for their documents about how long since the machine had been maintained or anything like that. We just asked for this small grade of expanded metal.
Q. Is this the, when you said it was at an angle, is this the angle you're talking about (indicating)?
A. Yes.
Q. Now, Dr. Buller yesterday, I think he testified, and he used one of his exhibit books and he put it straight up like that.

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A. Right.
Q. Does expanded metal ever get like that?
A. No, it can't, because, remember, it's lying flat and these strands are -- are stacked like this at an angle and if you tried to put these up at 90 degrees instead of having this slant, you'd have a staircase and if you had a staircase, well, now, now your reference is up here. You've tilted the whole thing.
So it would require a staircase going up off the screen to get to 90 degrees.
Q. If we measured in the radial direction right here (indicating) on the surface, would that include some air?
A. From -- from here down to the surface, that would have to include in air, yes.
Q. Now, Dr. Snyder, if you would look at some more photographs on this experiment, 15011 through 14, and 15276 and 15280.
A. Yes. These are pictures illustrating the process we used, many of the steps we used to make these stents out of expanded metal and then some pictures of the finished result.
MR. BADENOCH: Your Honor, I would offer these exhibits, 15011 12, 13 and 15276 and 15280.
MR. DISKANT: I think you went too fast for me. Are these all photographs?

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MR. BADENOCH: They're photographs of a stent that was made for the experiments. December.
MR. DISKANT: Read off the numbers again.
THE COURT: I heard no objection?
MR. DISKANT: I think not. He just went too fast with the numbers.
MR. BADENOCH: I'm sorry. 15011 through 14, 12, 13, 14.
MR. DISKANT: No objection.
MR. BADENOCH: 15276. And --
MR. DISKANT: One five -- no objection.
MR. BADENOCH: 15280.
MR. DISKANT: No objection. I'm sorry, your Honor.
*** (Documents referred to above were received into evidence.)
BY MR. BADENOCH:
Q. Let's look at the first of these, 15011.
What do we see here?
A. So this is kind of the second step in the process. What we did was take this expanded metal and cut it into basically a little square, about a half-inch on the side. And here we have a little metal rod that was just a convenient thing to fix it on and a piece of plastic tubing around that.

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And by simply taking expanded metal and rolling it around by hand, rolling it around this tube, here we have it tucked, rolled around the tube and then we used a little piece of soft rubber tubing, just to kind of pin it in place for the time being.
Q. Let's look at 15012, the next one.
A. So this is the next step in the process. What we did was sort of, just under a magnifying glass, kind of squish this tube back and forth until these joints were lined up and then this is a little bit of silver grazing paste that was just dabbed onto each of these joints.
And then the next picture, what we did next was use laser -- a laser welder. These have commonly been available since the 1960's, and just a little bit of zap of the laser on each of these spots melts the brazing paste. You can see all kinds of crud and stuff that's left over from the paste.
Q. Let's go to 15014.
A. The next step was to electropolish, as I think everyone has agreed has been available for a long, long time. It has been understood since the 19th century.
And after polishing, of course, all the extra material is removed and you see the shiny surface that I think Dr. Richter described.
The other thing we did, as Dr. Ersek says in

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his patent, that it's a good idea to smooth the leading edge, and we did one of two things. One was just to take a little pair of snips and snip off any little hairs that were there after the material had been cut with scissors and then the other thing was just to take a little bit of common fine sandpaper and just rub the end to get rid of those little hairs.
Q. Now, can we look at the next one, please? 15276.
A. So here in the -- the electro microscope gives you an opportunity to examine one of these things. It's on one of these little metal rods. Here you see it from above the diamond cells. Here, of course, you see your zig-zags going up.
I talked about the fact that these don't get to 90 degrees. When you wrap this around a tube, you see where it bends in, are in these little areas right here, and that tends also to reduce the stacking of the pieces on top of one another, so you get much less than double height, of course, and if you don't go through any air, you always measure the same thickness no matter where you are.
Q. If you could turn in your book, there are some more photographs, I believe, of the experiment. And these are 15016, 15250, 15253, 15263 and 15305.
15263 is -- no. I'm sorry. 15263 is a

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comparison.
MR. DISKANT: Sure. No objection.
THE WITNESS: So these are additional pictures of our Ersek stent after we've smushed it down on the balloon and also some pictures of some other stents.
BY MR. BADENOCH:
Q. And just so the record is clear, I was talking with counsel about those, but I think I want to offer those numbers, your Honor, and he did not object, but I think in our conversation, we didn't get it on the record.
MR. DISKANT: I'm sorry. I did not object.
THE COURT: All right. Do you want to say those numbers again?
MR. BADENOCH: I'm sorry. 15016, 15250, 15253, 15263, and 15305.
*** (Documents referred to above were received into evidence.)
BY MR. BADENOCH:
Q. Now, could we turn to those pictures, Dr. Snyder --
A. Sure.
Q. -- and describe what they show.
A. A crimped stent. I was having my -- having a hard time holding my hand steady here. Here, you can see this kind of greenish blue is a standard an angioplasty balloon and here you see the stent after it has been

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squished down on the balloon and then in the electron microscope, you get a clearer picture. You can see the little folds in the balloon and you can see the slots in the stent after it has been squished down.
Q. Now, just so it's clear, these are stents that you made from expanded metal like Ersek?
A. Yes. These are exactly what comes out of the process I just showed you, just wrapping the expanded metal around the tube, joining the points, cleaning it by and polishing it and then just taking a standard balloon and putting it on.
Q. Okay. Let's go to the next one. And this is a comparison.
Can you explain what you are showing here?
A. This is just a closeup from the previous slide, so this is showing several cells of this crimped Ersek stent and here's a picture of a crimped Palmaz/Schatz stent that I think we saw earlier and then this is a bare Palmaz stent, before it has been crimped.
Q. Now, could you look at Exhibit 15168 in your -- with the physical exhibits you have there?
A. Yes, I have it.
Q. And could you explain what that is?
A. Yes. This is -- we made a number of these and this is one of the leftovers as it were. This is one of the

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Ersek stents, saying it's on the angioplasty balloon in the package.
MR. BADENOCH: And we would offer, your Honor, 15168. That was an example of one of the stents used in the experiment.
MR. DISKANT: I object to that, your Honor. It's a demonstrative.
MR. BADENOCH: Very well, then. If it's a demonstrative, is it --
BY MR. BADENOCH:
Q. Dr. Snyder, could you come down and place that on the Elmo so that we can -- just describe to the jury what that is?
(At this point the witness stepped down from the witness stand and approached the Elmo.)
THE WITNESS: So I think we've seen a couple of these before. You've seen these long tubes that are used to protect these devices for packaging, so here's the angioplasty balloon, the connections used to puff up the balloon. And I will pull it out.
So at the end, I don't know if this zooms any better, but at the end is this little plastic sheath that's there so that you don't damage the stent when you put it in.
So here's the -- here's the catheter and you

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see these little gold-colored markers. Those are the radial peg markers that the cardiologist can use to see where the balloon is.
And in between is the balloon itself, and you can see the stent on the balloon, and I think you can probably just barely make out those little members and the little -- the little slots. I don't know if it helps to rotate a bit.
BY MR. BADENOCH:
Q. I think that's fine. Thank you, Doctor.
(At this point the witness then resumed the witness stand.)
BY MR. BADENOCH:
Q. Now, Dr. Snyder, is that what you just showed the jury one of the stents that you actually made from expanded metal?
A. Right. We made a number of them and used three of them in doctor -- the experiments. That was one of the ones left over.
Q. And is -- did Dr. Low actually implant that one in the artery of a pig?
A. No. That was one that was -- was left over after he had used three of them.
Q. Did you watch Dr. Low implant those stents in the artery of pigs?

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A. Yes, I did.
Q. And were the balloon catheters withdrawn from the pig after the stents were implanted?
A. Right. After they were implanted, of course, after you inflate the balloon and deploy the stent, you deflate the balloon and pull it back out, leaving the stent behind. And what Dr. Low did to test the balloon was reinflate the balloon to its full pressure and then we went to a stereo microscope and we looked at it and turned it around and still held all its water and had its sausage shape and the outside of it looked completely fine.
Q. So there was no puncturing or shredding of the balloons?
A. No. We couldn't see any damage at all to the balloon.
Q. How long did it take to make the Ersek-type stent you've just described?
A. Not long. They didn't have all the equipment in one place. There was a lot of sort of walking from bench to bench because they weren't really set up to do this. And my estimation, it took about half an hour to make each one.
Q. How long did it take for Dr. Low to implant them?
A. A minute or so or something. You know, I think

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he'll describe this. He goes in with the guide wire and finds the coronary artery that he wants to put the stent in and it seemed to take him half a minute to thread the thing up and half a minute to deploy the balloon, and he reported no issues with pushing the catheter or anything like that. He just described it as an entirely routine, I think piece of cake were the words he used.
Q. Was there any indication that they shredded or cut the artery?
A. No. Of course, you're watching on the X-ray machine the kind of video X-ray machine as you do this, and you simply saw the stent deploy. I'm sure Dr. Low could describe this better, but basically what you saw was the vessel with the -- with the stent in it, just sitting there, looking wide open and so forth.
Q. Were the pigs fine afterwards?
A. Apparently, yes.
Q. The -- was the type of expanded metal that you used available in 1985?
A. Yes. We talked to the manufacturer and they reported that they had been making all of these different sizes for a very, very long time and in basically the material of your choice for a long time.
Q. What conclusion do you draw from these tests?

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A. Well, my conclusion is that there's just no basis for Cordis' original contention to the Patent Office that this, A, had nothing to do with a stent, or was somehow a structure that couldn't be used as a stent, and that also their contention that somehow this material was inherently sharp or dangerous or damaging or anything like that.
Q. Did Cordis do any experiments of its own, to your knowledge, to support Dr. Andros' or their contention about this?
A. To my knowledge, absolutely nothing.
Q. Do you know if Dr. Buller has done any experiments to support his contentions about Ersek being sharp and shredding the arteries?
A. To my knowledge, he has no support of any kind.
Q. Now, we've been discussing the Ersek patent. Let's reorient ourselves.
What portion of the obviousness analysis have we been talking about so far?
- - -
A. We've been talking about the content of the prior art. So, remember, we're looking at the prior art that's relevant, seeing what it says and what we've been talking about all this time is reading what Dr. Ersek says and applying what he says.

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So this is the content of the prior art.
Q. Let's go to the next step, then.
Did you compare Claim 23 in the limitation with Ersek?
- - -
A. Right. Yes. And so, of course, the next step is to look at what Claim 23 says, look at what Ersek says and check whether Ersek has already described everything that is in Claim 23. If not, we'll make a little catalogue of the differences and see how important they are.
Q. And I want to go through these, but basically, did you find any differences when you compared Ersek with the claim?
A. There were a few differences in what I would call the design details. Any time you make anything of any kind, there are always little design details that you choose, that you might think are ideal and the differences are only in these little details that are just obvious for one to change or adjust.
Q. Did the differences in these details make any difference in the functioning?
A. No. It's still an expandable tube. It still has two diameters. It's still capable of supporting the lumen. It's still plastically deforms. It's still

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stapler?
A. Yes, I remember that.
Q. Do you remember him saying that it went bang when he used it?
A. I remember that, yes.
Q. How does it actually work?
A. Well, this instrument looks very much like -- this is 1970. This looks very much like your common minimally invasive surgery tools that surgeons use today. If you need to get your gall bladder out or something, they no longer do it through open surgery. They do it through small holes in your skin. They do it with instruments that look exactly like that. They have some kind of slender shaft. They're usually adjustment knobs and flops to rotate the other end and so forth. They usually have this kind of handle.
It turns out I've actually done some work with a surgeon who's interested in tool design and he has described to me how, kind of surprisingly, these just general simple handles are very attractive to surgeons because of the fact you can hold them in different ways and you can hold them in your whole hand when you want to squeeze them hard. And you can squeeze the side of it and use your ring finger or opinion key when you want a soft touch and so forth. So they're

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very versatile.
What happens when you pull on the handle is that these little rubbery washers here get squeezed. Of course, rubbery materials, when you squeeze them this way, they squish out in this fashion, and the more you squeeze in this direction, the more it squishes in the radial direction, and so, by pulling this handle a lot, pulling it a little, using a soft touch, using a hard touch, you can control how much the device gets expanded.
Q. So does that make the Ersek device, then, controllably expandable?
A. Right. That's what, you know, what the surgeon is doing, is pulling a handle just enough and, of course, the surgeon can see the vessel, and watch for the vessel to be puffed you've to what, in the surgeons judgment, is the right amount.
Q. Let's go back to the final limitation of the claim, which was the one added by Claim 23, the smooth surface limitation.
Did the Court give a definition of that?
A. Yes.
Q. And this is the definition: The outside of the wall surface of the unexpanded tubular member has a continuously even surface, without roughness, points, bumps or ridges, especially to the touch.

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A. Correct.
Q. Did you consider that definition?
A. Yes, I did. And, you know, I felt this material and when you rub your finger over it, it feels basically like window screen, like aluminum window screen would, and so it's not especially rough to the touch, but it does have bumps and ridges. And I would not say that this really has a smooth surface.
Q. Does the fact that it's rough like window screen mean that it would cut?
A. No. I mean, you rub window screen, it doesn't cut your hand.
Q. Does it affect how the device operates?
A. No, not at all.
Q. Does it affect whether or not you can controllably expand it?
A. That's unrelated.
Q. Or whether it's deformable?
A. Unrelated completely.
Q. So let's summarize, then, what your conclusions are comparing the limitations of Claim 23 to the Ersek device.
Do you agree -- well, why don't I let you give the summary here.
A. We've completed our checklist. It's an expandable intraluminal vascular graft, it's a thin-walled tubular

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member, has first and second seconds. First and second diameter. It has characteristics that come out of plastic deformation. The only thing left are these, basically, design details that are optional, that don't have anything to do with being insert able, being expandable, being able to support a lumen, and those are the wall surface, the uniform thickness and the smoothness.
- - -
Q. Do these design details affect the operation in any way?
A. No. As I said, you can still insert it. You can still expand it and it will stay at its second diameter. It will still support the lumen.
Q. What is you conclusion as to whether or not a person of ordinary skill in the art would be able to make any modification of these design details?
A. I think that would be obvious how to do that. It's kind of right before you.
- - -

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Q. Was there a specific motivation in the art to make any such changes if you needed to?
A. Well, the first motivation is in the Ersek patent itself.
Q. And could you describe what you are talking about?
A. Yes. I think we might have an excerpt. But regardless, remember what Dr. Ersek says. I don't know -- here it is on the screen.
So this is out of the Ersek patent from Column 3, so that would be on the second page of text.
He says, the edges may be cuffed if desired or simply smoothed to facilitate entry.
I think it might be in this brochure. I don't recall whether it's in this particular brochure from the manufacturer, but even the expanded metal manufacturers sell the material with some of the ends kind of tucked over like the cuff of -- of pants, and that gets rid of these little hairs that we -- we talked about, and makes the edges smoother.
And what Dr. Ersek says is you might want to do that to make it easier to slide the thing in, or he said you might just smooth it off.
What we did was just take a little sandpaper and smooth off those hairs.

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So he's telling us, you might be interested in seeing how smooth it needs to be in order to -- to make it insert able for your application.
Q. Now, is there another source of motivation to make any design changes you might need?
A. Sure. Remember that the problem that this person skilled in the art is trying to solve is the frustration that we heard about early in the trial, with the results of current stents and not having a stent design that seemed to serve every purpose as well as people hoped.
And so there's this whole art of common practice in stenting and delivery and so forth that one could apply.
Q. And when you talk about the problem this person is trying to solve, are we talking now about Dr. Ersek or a hypothetical person or what?
A. This is the hypothetical person.
Q. In 1985?
A. In 1985, who knows about balloon angioplasty, knows about insertion of stents, and so forth, and is frustrated by not having as good a stent as he or she might like.
Q. Is someone who knows about what Dr. Gruntzig said in the lecture about problems --
A. Knows, has read everything.

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Q. Is there another source of motivation to adjust these design details?
A. Well, there's just what one commonly knows. Remember, there's an engineer and a physician working here, so if an engineer is faced with a problem or an issue, there are logical things that engineers do.
Q. Have you also considered the abstract, Dr. Palmaz's abstract for the radiology meeting in 1984?
A. Yes, I have.
Q. And can we have that?
And, first of all, is it your understanding that, even though Dr. Palmaz wrote this, is this in the part of the prior art?
A. My understanding is there's no argument about that.
Q. Okay. Now, let's look at what Dr. Palmaz says. He says, in an attempt to overcome the problem of restenosis after vascular balloon dilatations, we have developed an expandable intraluminal graft that allows dilatation of the lesion and simultaneous placement of a supportive endoprosthesis to prevent recoil of the arterial wall.
What does that mean to a person skilled in the art?
A. Okay. So, of course, we're reading about kind of news. This was the section, you recall, about what's

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new in stenting, where people might come and have eight minutes to say what their new ideas are, and this is what Dr. Palmaz says.
He says, in an attempt to overcome the problem of restenosis, so after balloon angioplasty, or he calls it vascular balloon dilatations. And this is what we talked about. People were commonly doing balloon angioplasty. Sometimes you had restenosis and people were seeking different ways, including already applying stents, to fix this.
So this is the problem that he's trying to solve. And he says that quite clearly.
Then what does he say? In order to solve this problem, he says, we have developed an expandable intraluminal graft.
He doesn't say he developed any other new kind of gadget. He says he developed a graft. And anyone reading this would understand the graft in a medical dictionary is the thing that you leave behind in a body that wasn't there before.
So he has developed a new kind of graft. And what's special about this new kind of graft that we might want to come hear about?
The new kind of graft allows dilatation of the lesion. Now, of course, the only method known at

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the time or the only method commonly practiced at least to do dilatation was the balloon. And the reason for that, it's very important, is, I think as you've heard, that this plaque is very, very hard and takes very, very high pressures to expand it, and basically to break it open.

And I think Dr. Low will explain some of that.

And so it required these noncompliant high-pressure balloons to provide enough pressure to crack open this plaque.

So he's saying that this forceful dilatation of the lesion occurs simultaneously. It occurs at the same time that you are placing the supportive endoprosthesis, the graft, whose purpose is to prevent recoil of the arterial wall.

So he's talking about a new kind of stent, and he's talking about a stent that allows the dilatation, balloon dilatation being the only thing practiced, to occur at the same time that the stent itself is placed in the lumen, in contrast with the previous literature of self-expanding stents, where you did the balloon first, and then came back with an insertion tool for the stent.

Q. Now, Dr. Snyder, Dr. Buller testified yesterday about, no, this could be a spring stent, which is simultaneously dilating and being implanted.

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A. Right. That was one of his alternatives that he proposed and that simply can't be. It's just not possible.

Q. Can we look at the Gianturco patent that he referred to, the '568 patent?

And can we go to the next page?

What is being shown here in Gianturco?

A. This is -- this is a lumen and Dr. Gianturco explains in the text, and then Dr. Low glanced at the figure and immediately says what it was as well. This is a vessel and, most likely, this is a vein. And most likely it's a vein in the upper chest. And this is a tumor, a cancer that has grown in this individual's chest and it has pushed down upon the lesion. It's interfering with blood flow in the vein.

Remember veins are the return to your heart and the pressure inside of a vein is very, very, very low. It's incredible how well blood flows through your veins with hardly any pressure driving it.

Q. All right.

A. Next, Dr. Gianturco is explaining the insertion of this spring and the spring starting to be popped out of the insertion device into this narrowing.

Q. Can we go to the next page?

And here it comes out and pushes the tumor

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aside?

A. Correct. Now, it is pushing the tumor aside, and it's possible that the tumor is soft, so perhaps Dr. Gianturco is correct, that this could happen.

If the tumor is hard and the tumor is not mobile at all inside the body, then what Dr. Low explained to me is what would happen is, since this is a vein and veins are kind of floppy, it would really get pushed out on the other side, so if it was a rigid immobile tumor, this side would still be down and this side would just get pushed out. And this is because you're just not dealing with very high forces.

Q. And does a spring stent like Gianturco have enough force to break plaque?

A. You know, in principle, maybe you could use heavy enough wire. But think about it. If it's pushing hard enough to break plaque and it has to keep pushing all the way until you get out to that final diameter, there's no way for the spring to know where to stop, as it were.

So, by definition, a spring that's strong enough to push the vessel all the way to this final diameter is going to be strong enough to rupture the vessel. Of course, that's the sort of tragedy that people refer to.

Q. So what is your conclusion about what the Palmaz

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abstract teaches, then?

A. That we have not escaped the idea that it's a stent upon balloon.

Q. So balloon expandable stent?

A. Right.

Q. And what's your conclusion about the differences, then, between Claim 23 and Ersek?

A. My -- my conclusion is that Ersek, the Claim 23 is obvious in light of Ersek, and with motivation, if you need it, from the Palmaz abstract.

Q. And also you indicated from Ersek and the problem itself?

A. Correct. Yes.

Q. Now, let's turn to the last part. Did you consider secondary factors?

A. I considered some secondary factors, yes, and I heard about a lot in the trial.

Q. Well, talking about what we heard in the trial about the commercial success of the Palmaz stent, did you consider that?

A. Yes, I did.

Q. And did it affect your conclusion?

A. No, not at all, because I think what -- what we've -- what we've heard about is all of the different things that go into a successful product, from all the

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aspects of the design of the stents to the delivery system and so forth, and we also heard that stents really didn't become the treatment of choice until long after Dr. Palmaz did his work and others started introducing improved designs.
Q. Did you consider the skepticism of doctors when Dr. Palmaz was trying to get people to start using his device?
A. Yes, I did.
Q. Did it affect your conclusion?
A. No. And remember, we need to focus on Claim 23. We're not -- the focus here in analyzing Claim 23 is not balloon angioplasty. The focus is on can you make a device that can go into a lumen, expand and stay expanded, and that has nothing whatsoever to do with -- with all this other stuff. So there was no -- no skepticism that you could make a slotted expandable tube. You can see that.
There was skepticism whether it was useful in Dr. Palmaz's application that he was trying to promote.
Q. Did you consider all of the awards that we have heard about that Dr. Palmaz received?
A. Sure. And, again, it's very important to separate the credit someone gets for being an entrepreneur or for promoting it, for refusing to give up when you get no

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thank you letters. That's the energy and enthusiasm and refusal to give up for which Dr. Palmaz has gotten all this credit.
What's inappropriate is to take the accolades he has gotten for his enthusiasm and assume that that somehow means his patent covers everything about coronary stenting or stenting in general or expandable tubes for that matter.
Q. Now, so what is your conclusion after considering these as to whether or not Claim 23 is obvious in light of the prior art?
A. My conclusion is that to one skilled in the art in 1985, reading the prior art, Claim 23 would be entirely obvious.
Q. All right. Dr. Snyder, I'd now like to turn to the different question of infringement. Your opinion, again, on whether or not the NIR stent infringes Claim 23 is what?
A. My opinion is that the NIR stent does not infringe Claim 23, because it lacks this wall surface, having uniform thickness.
Q. Or substantially --
A. Substantially uniform thickness. Thank you.
Q. And, briefly, can you look at the -- well, briefly, if you can just explain why does the NIR stent not have

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a wall surface with substantially uniform thickness?
A. Again, remember the relevant thing is how much space do the members take up, how much space does the wall take up. And so here's our -- our little fixture that represents whatever delivery system you choose and we're measuring the wall thickness and in this area, the wall thickness takes up this much space, and in this area, the wall, due to the protruding U in this example, takes up this much space. It's simply variable.
Q. Now, Dr. Snyder, I think we have some photographs of NIRs. They are DX-15083, 15050, 15054, 15061 and 15078.
Can you identify those? Do you have them there?
A. These are all electron microscope photographs of NIR stents.
MR. BADENOCH: Your Honor, I offer those numbers, 15083, 15050, 15054, 15061, and 15078.
MR. DISKANT: No objection.
THE COURT: Thank you.
*** (Exhibits referred to above were received into evidence.)
BY MR. BADENOCH:
Q. Can we look at these pictures and describe what they show on the NIR stent, Dr. Snyder?

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A. Sure.
Q. What do we see?
A. Here's a view looking down at a NIR stent and you can see the C regions. The focus isn't -- the lighting really, the exposure is not quite right here.
But you can see, for example, the C regions that lie pretty much flat, maybe not precisely on the delivery device, and you can see these U loops that regularly protrude because of the way the pattern was wrapped around the tube.
Q. And are these U loops protruding uniformly here?
A. Right. You can see one, two, three. It has been wrapped around in this direction and there's nothing to keep these from sticking out.
Q. Let's go to the next one.
What do we see here?
A. Another picture of the same thing. We're looking down a stent. We see the C's lying on the stent. They do twist a little bit and you see the U loop sticking out here, a U loop here and a U loop here. And in this particular view, you also see these welds of the stent.
Q. Is this a substantially uniform cylindrical surface, in your view?
A. No, not at all.
Q. Let's go to the next one.

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it's substantially uniform.
Q. Okay. Now, could you describe the measurements?
A. Sure. I took measurements in two ways and the first way was using an instrument called a Conn focal layer distance gauge and this is a common instrument used in industry to make very precise measurements. And I can illustrate, I think, with my laser pointer and my pen, basically how this works.
It's basically a machine where you have a fixture that can be rotated around and moved back and forth, and you have an optical system of a laser that shines down upon it. And my measurements of focal distance, not entirely different from some camera range-finders. You get very, very precise measurement of the height of each feature everywhere that you want.
And here's, remember, our drawing of the variations that we're looking at, the flatter C regions, the protruding U's and the protruding welds, and there it is in profile.
And I think in the next slide we show -- here's a comparison with what --
Q. Well --
A. I'm sorry.
Q. I -- let's go back to the other one.
This measurement here (indicating) that you

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took, is this one consistent with the way Cordis said that you should measure wall surface?
A. It's completely consistent, yes.
Q. Is it consistent with the way Dr. Buller says you should measure wall thickness?
A. No. So it's consistent with what Cordis said to the Patent Office. It's inconsistent with what Dr. Buller contended at trial.
Q. Did you also measure strut thickness?
A. Yes. As a reference.
Q. Let's go to that. I think it's Slide No. 30.98.
Is this the --
A. This is the chart that Mr. Diskant tried to play a little trick with on the first day of Doctor -- with Dr. Buller. This is a chart in a report I gave to Cordis, which was a compilation of strut thickness measurements.
Now, this is the thickness of the metal, not the thickness of the wall. And I obtained these measurements as a reference for how much the wall varies compared to the struts because that tells us, how the wall varies compared to the thickness of the struts, because that tells us as a percentage how much the variation is.
And so these were measurements of strut

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thickness, and this is the title from the chart, and I submitted lots and lots of text, explaining that this was the strut thickness, and it was not the wall thickness, and these were the numbers that --
Q. Okay.
A. -- that we obtained.
Q. Okay. Let's go, then, to the results of your measurements on wall thickness. Can we go to that?
A. Yes. These are the points.
Basically, when I measured wall thickness variations, what I did was, for each U loop, I measured the height of the -- of the loop at the middle, right here. I wasn't able to catch the edge with the distance gauge. And the height of each C and these relative measurements are this height compared with this height.
Q. And then --
A. For each individual U.
Q. These are your results here?
A. Right. So on average, on average, the U loops protruded by their nearest neighbor C loops by 2.4 thousandths of an inch, which is about 65 percent of the thickness of the struts.
Some U loops protruded as much as four and a half thousandths of an inch, which is 125 percent.
Q. How many of them protruded by over a hundred

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percent?
A. I think that's on the next slide.
So there were 58 U loops that I measured and, out of the 58, 11 of them stuck out more than a hundred percent of the thickness of the material, so 19 percent of the U loops stuck out more than the original thickness of the material.
Q. And so we have a summary of your conclusions on this?
A. Right. So here's a summary. Typical U loop sticks out 65 percent. Maximum, this is on -- an individual stent, 125 percent.
- - -
A. (Continuing) And 19 percent of them were more than 100 percent.
Q. So did you also -- and I don't want to go through it in detail, Dr. Snyder -- did you also try other measurement techniques?
A. I used another measurement technique called an Optical Profile Memory, a machine which basically looks at the device in shadows.
- - -

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A. (Continuing) : And as the material is rotated, you can catch the high points and the low points and measure the differences between them.
Q. Did you also measure the weld?
A. Yes, we did measure the weld.
Q. And could we look at the results there? I think it's -- looks like 108.
A. Here is the weld thickness and the average weld thickness, here it is in thousandths of an inch, and that is 74 percent on average more than the original strut material.
Q. So the weld thickness is in this range where we have to use judgment whether or not it's largely --
A. It's high up in that range, but it is in that range where we need to apply judgment.
Q. What is your judgment?
A. My judgment is this does not make it substantially uniformly thick.
Remember that this amount of protrusion of these struts is going to add more than 10 percent to the crossing profile and to a physique go a device that's going to fit nicely into the smallest area, that's -- that's a lot.
Q. And then the protrusion of the U loops, that went

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out the hundred percent limit?
A. That's right.
Q. So what's your conclusion, then, under the Court's definition of whether or not the NIR stent infringes?
A. The NIR stent can't infringe Claim 23.
MR. BADENOCH: Thank you, Dr. Snyder.
THE COURT: I think perhaps we'll take our lunch break before we start cross-examination.
Ladies and gentlemen, I will just remind you not to discuss the case among yourselves during lunch.
(At this point the jury was excused for a luncheon recess.)
(Luncheon recess taken.)
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AFTERNOON SESSION

(Proceedings resumed after the luncheon reces

THE COURT: Let's bring our jury in.
(At this point the jury entered the courtroom and took their seats in the box.)
THE COURT: Mr. Diskant?
MR. DISKANT: Thank you your Honor.
CROSS-EXAMINATION
BY MR. DISKANT:
Q. Good afternoon, Dr. Snyder.
A. Good afternoon.
Q. Let's first talk about the question of infringement, if we could.
MR. DISKANT: Could we have 37484 on the screen, please?
BY MR. DISKANT:
Q. You've given a lot of testimony about what you think did or did not happen in the Patent Office. Do you recall that on your direct?
A. I recall discussion about what happened at the Patent --
Q. Okay. You offered your interpretation of what

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happened; is that right?
A. I don't recall anything about what didn't -- I'm not sure what you mean.
Q. All right. In any event, you understand that the question for infringement, of whether the NIR stent infringes Claim 23 of the '762 patent requires you to take the claim language as construed by the Court and consider it against the NIR device; is that right?
A. Right. I don't recall talking about the Patent Office when I talked about infringement.
Q. That's the point I am making with you right now.
A. Okay.
Q. The question of infringement has nothing to do with what happened in the Patent Office. The question of infringement has to do with taking the claim limitation as defined by Judge Robinson and applying it to the NIR device; correct?
A. It's comparing the claim language as construed by the Court to the accused device, yes.
Q. That's it; right? That's the analysis?
A. I believe that is the analysis.
Q. Okay. So we have a wall surface having a substantially uniform thickness, which Judge Robinson has defined means, the wall of a tubular member, and that's the stent; right?

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Q. And how long have you been practicing interventional cardiology?
A. Well, I was fortunate in that I started my training in the seventies and I finished my fellowship in 1980. And during my training in cardiology, my professor, who was in charge of the Cardiac Cath Lab, had gone to Zurich to work with Dr. Gruntzig and brought back the balloon catheters and inflation devices. So I really got to do it starting in my training in 1979.
Q. And about how many stents do you implant in a given year?
A. I would estimate that I implant about 500 stents annually.
Q. And do you implant all of the major commercially-available stents?
A. I have throughout the time that stents have been available. I've used virtually every commercially available stent. At the present time, as you know, the preferred treatment is with drug-eluting stents, so we use either the Taxus stent or the Cipher stent, both of which are melts stents that are coated with medication that prevents the scar tissue from coming back.
Q. And have you participated in any clinical trials for any stents?

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A. Well, I've participated in a large number of these multi-center randomized trials and some registries, beginning with the new generation stents in about 1996 or so. I've participated in the Multi-Link, the NIR stent trial and virtually all of the stents that were introduced subsequent to that.
Q. Dr. Low, were you in court this morning with Dr. Snyder -- when Dr. Snyder explained how he had expanded metal Ersek stents built?
A. Yes.
Q. And did you implant three of those Ersek stents into the coronary arteries of a pig?
A. I did.
Q. And did you prepare a report of that implantation procedure?
A. I did.
MR. CHAPMAN: Your Honor, if I might approach the witness...
THE COURT: Yes, you may.
BY MR. CHAPMAN:
Q. Dr. Low, I've handed you DX-15168 (handing exhibit to the witness).
Can you identify what that is?
A. This appears to be a stent like the stent that we used to implant in the animal. It looks like an Ersek

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expanded metal stent.
Q. But you didn't implant this one in the pig, obviously; correct?
A. No.
Q. And why -- is it common to use the pig for animal studies like this?
A. Well, the testing for stents is -- has always been done in the porcine model or the swine model and that's because the pig model is very much anatomically like the human heart in terms of the size, the shape of the arteries, the size of the arteries as well as the distribution of each of the arteries.
So virtually all of the stents that are done before a stent is even tried in a human, the FDA requires that it be done in a swine or pig model.
MR. CHAPMAN: Can we have DX-20.16?
BY MR. CHAPMAN:
Q. Dr. Low, this is DX-15016, which is already in evidence.
Can you describe what this is, please?
A. May I use the pointer?
Q. Sure.
A. I think it's very clear that this is the metallic stent and this is crimped on a balloon, which is overlying a green catheter.

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And this is a little protective device that is used to slip over the stent, to protect it until it's used.
So the catheter, then, is hooked up to an end that has a hole all the way from the back end through the tip and that's the channel where we thread the guide wire, to lead us into the right blood vessel and to the right location.
There's a second channel in the shaft that inflates the balloon and that's -- that comes off a separate channel and it's connected with what is called the Y connector to an inflation device.
The inflation device is a little syringe-like device that we can get some mechanical advantage with and increase the pressure and there's a dial like a power gauge so you know exactly how much pressure you are putting into the balloon for expansion.
Q. Is this one of the expanded metal stents that was implanted during the procedure?
A. No. This is a photograph. I can't tell you if this is a photograph of when we implanted, but it's a photograph of one that looks just like this one.
Q. Was the photograph taken at the animal lab where the study was performed?
A. I believe it was.

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Q. And when you were doing the stent implantation procedure in the pig, did you take angiographic images of the procedure?
A. Yes. The procedure that we did is very much like what we would do on a patient, so instead of a human patient, we have a pig patient.
And so we make the exact kind of X-ray pictures, and I did the procedure exactly like I would on a human. And I would do it exactly like this when I'm asked to implant stents by the different manufacturers for the chronic studies for the FDA, before they are actually used for clinical trials.
Q. And do you have a movie which shows the procedure taking place?
A. I do.
MR. CHAPMAN: If we could play that...
BY MR. CHAPMAN:
Q. Now, just before we begin, Dr. Low, is this an angiogram?
A. Yes. An angiogram is an X-ray picture, and it's an X-ray picture that involves injecting an X-ray contrast material that has iodine in it. So as we pass X-ray through the animal or the patient, the X-ray contrast media is clear. But since it has iodine in it, if you inject it into the artery, it blocks the X-ray from

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penetrating through the artery so we get a nice shadow of the artery itself.
So this is how we make angiograms. We run a little tube up to the heart, called a guiding catheter. This tube comes in various sizes. This one happens to be what we call seventh French. And we know the diameter is 2.33 millimeters. We use that to help us calibrate the size of the artery. And through that catheter we inject X-ray contrast which outlines where the blood would flow in the artery.
So what we're seeing here as it plays is the actual inside channel of the blood vessel. And as you can see, the blood vessel starts off as a very large channel and then every time it gives off a branch, it gets a little bit smaller. When it comes down -- gets down to the tip, it becomes quite small.
It's a tapering size from the beginning down to the tip.
So this is an angiogram and it's being looped and when you see back here that looks like smoke is the actual X-ray dye that's extra, that's being diluted by blood that doesn't have X-ray contrast, so you shouldn't be distracted by that. You should only know that it's being washed through the rest of the blood and then being cleared out by the kidney.

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So this is a picture of the right coronary artery that runs around the right side of the heart. It goes to the bottom surface of the heart. We're looking right through the heart. This is the posterior descending branch, the right coronary artery.
Next slide.
So during the procedure, the catheter was advanced over the guide wire and under X-ray control we get it into the right spot. After we get it into the right spot, we have to make sure that the catheter is not blocking off the blood flow, so we're constantly monitoring the pressure at the tip.
So the only time that we stop monitoring that pressure is when we actually inject the X-ray dye because, if we blocked off the artery with the catheter, then that would be starving the heart muscle of blood and essentially causing a heart attack. So you can't interrupt the blood supply for very long.
So this picture -- and it's hard to see, but you'll see a little wire down here at the tip. So the wires we used are 14 thousandths of an inch guide wires with a spring tip that can be shaped. When you put a bend on the catheter tip or wire tip, we can essentially steer it in any direction, so we can advance it and turn the wire to get into any branch that we want to go into.

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Now, the tip is made of platinum, which is much more X-ray opaque than the stainless steel shaft. And we want to only see the tip because we don't want to be distracted by the rest of the wire.
If you look very carefully, you can see a faint shadow of the wire, but what we really want to see is where the tip is because we know where the rest of the wire is.
So in a normal case, when you can see it in a dark room, you can see the thin guide wire with a platinum tip.
Next slide.
So after we take that picture, we can then advance a stent on a balloon to the site where we want to deploy it. And the way we tell where we are is that the balloon, at its ends, has platinum or gold markers, so it's very bright. But they're very small dots, so it's very difficult to see.
But once we do that, we can then inject some dye around it and if we're sure that that is where we want to place it, that's how we find the location.
Now, in a normal patient, there would be a blockage there, but in this case, there's no plaque buildup in the coronary arteries of pigs. We just decide to deploy it in three different locations.

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So this is a location we were pleased with. Then we go on and deploy it.
Next slide.
Next.
Okay. This is a more magnified view and now we've injected X-ray contrast inside the balloon so that we know it's being fully inflated. And now you can see the dots a little more clearly, because we're using a magnified view.
Now, we don't always use magnified views because it takes more X-ray. And so we don't want to cause X-ray injury to the animal or to the patient.
So to illustrate this better, it was a magnified view. And you can see the dots marking where the stent would be, be inside those two dots. And we know the balloon is inflated now because the X-ray contrast is filling the balloon.
Next slide.
So once we've done that, we deflate the balloon and pull out the balloon. Now the stent is left behind and then the guide wire remains in place.

- - -

A. (Continuing) So we finished implanting the first stent in this location. And because it's fully against the vessel wall, you don't see anything abnormal.

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In a dark room, looking up very closely, you can see a very fine cross-hatch that represents the stent itself.

- - -

A. (Continuing) Furthermore, when you inject the X-ray dye, you see that there's no leakage and no damage to the rest of the vessel, so we know it's well implanted with no injury to the rest of the vessel.
Next slide.
So now we're putting in another stent and, if you look very carefully, there's a stent right up here and we're putting it more proximal, closer towards the opening of the artery, and we're going to implant the second stent.
The first stent was implanted further down here.
Next slide.
So once we're pleased with the location, we'll inflate the balloon again, and you can see here that the balloon again has been inflated and we've deployed another stent.
Next slide.
So then we deflate the balloon and we take a picture. And you can see that the stent is right here. There's a little hangup of contrast, so you kind of see where the turbulence is.

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Keep going.
And so we completed that and now we're introducing a third stent, and the third stent is going past the first stent, but not quite to the second stent. You can see it right in here.
So this is the third stent that we're deploying.
Now, remember, blood must constantly flow through the arteries, so you can't leave the balloon up very long or you would be interrupting the blood supply, and in a patient you would be causing chest discomfort. And if you leave it up long enough, you would cause heart muscle damage.
Okay. Next slide.
So once we've confirmed that we're in a good position, we'll go ahead and deploy the stent.
Next slide.
So this is a magnified view and you can see the inflation of the balloon again. So this is the third stent. Remember the first stent is here and the third stent -- and the other stent is here. Number one deployment, No. 2 deployment, and this is the third one.
Next slide.
So this shows an angiogram afterwards and you

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can see that the artery is wide open. We have not made any holes in the artery. There's no leaking of the X-ray contrast out any area of the artery, and, in addition, every part of the artery is wide open and the flow is very brisk, and it's exactly like it was when we started.
Next slide.
So now we've pulled out the guide wire and the three stents are deployed.
Next slide.
And here's a magnified view of the same thing. And you can see that where the stents are, because the stents have some rigidity, there's some change in the way the artery is contracting, but the channel itself is wide open and, again, there are no holes in the artery, no X-ray evidence that there has been any damage to the artery whatsoever.
So this would be exactly like what we would see in a normal patient.
Next slide.
So just to finish, we then have, you know, where the stents are and this is the final angiogram which we can play.
So this is the procedure that we perform and after we've performed this procedure, I generate a report, a catheterization report, exactly like I would do if I

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were doing it on a normal patient in exactly the same format.
Q. Now, how was the pig doing after the procedure?
A. The pig was doing absolutely fine.
Q. Okay. Was the pig under anesthesia when this was being done?
A. Right. Because we can't give conscious sedation to animals, we always intubate them and give them medications, and it would be like doing an operation on them.
Q. Now, would you describe the procedure as successful?
A. Very successful.
Q. Okay. And did you successfully deliver all three of the stents?
A. We delivered all three of the stents and, furthermore, we took the balloons out after each stent deployment. We inflated it to high pressure and there was no leakage from the balloon, so the stent crimping didn't cause any injury to the balloon itself.
Q. And you were able to successfully expand and implant all three stents?
A. Yes.
Q. All right. And how do you know you were able to successfully deliver, expand and implant all three

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stents?
A. Well, we watched the entire procedure under X-ray control and to be sure the stents are in place, we made angiograms during and after, which confirms their position.
Q. And was the blood flow through the stents after you implanted them satisfactory?
A. It was completely normal.
Q. Did you see any evidence of any injury to the artery?
A. None whatsoever.
Q. How do you know that?
A. Well, if we had injured the blood vessel, if we made a hole, there would be leakage and the animal would not be doing well. That's one thing.
Two is that if we caused any other kind of injury, there would be an X-ray picture of the injury. If you tear up the blood vessel lining, you would see a picture, a negative shadow of the X-ray lining inside the artery.
So I'm sure that any cardiologist that is familiar with angiography could look at this and see that there is no injury.
Q. Did the stents cut the artery in any way?
A. No. In fact, stents don't cut arteries. And the

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reason is because when we deliver them, they're crimped down on a balloon so it's smaller than the tube itself. And when you get there, you select the balloon size very carefully. And this is what makes excellent implantation from okay implantation.
You try to match the artery size to the balloon and sometimes we add about 10 percent maximum to the overexpansion. And the reason is because arteries are elastic tubes. They're not just one size. They may be one size at a particular time, but if you go running, they get bigger because your heart needs more blood vessel, more blood supply. If you are sitting and resting, they get smaller. There's auto regulation not only of heart arteries, but all arteries in your body.
So we pick the size that we think is going to fully deploy the stent against the vessel wall, so we want a balloon that's going to be touching every aspect of the artery and maybe stretching it no more than 10 percent.
So if every part of the balloon is touching the vessel wall and the stent is sitting on top of it, the stent is then imbedded into the vessel wall or the plaque.
And you can't injure it by cutting and so forth because the vessel wall is completely elastic. You

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can hold a knife against your -- the palm of your hand and you won't cut anything because you are not sawing back and forth, and you are not pushing against another heart surface. And that's how stents are imbedded. It's elastic. We expand the balloon until all of the balloon is touching the vessel wall, so whatever is sitting on top is gently implanted into the vessel wall and the vessel wall is thick with a thin inner lining called the intima, a media and the muscle layer will stretch and allow the implant and, you know, stents never puncture. The only way you would rupture a vessel is if you put a 3-millimeter -- in a 3-millimeter artery you put a 5-millimeter stent. You would exceed the elastic limit, you could possibly rupture. But we know the size of arteries and we calibrate them using the size of the guiding catheter and there are actually packages that allow us to make those measurements with the X-ray camera.
We stop frame with the pictures. We can do QCA, quantitative coronary angiography, and actually make the measurement or we can put in an ultrasound probe and make an even more accurate measurement.
Q. Just one last question. Did the stents that you delivered puncture the balloons at all?
A. They did not.

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Q. Okay. And how do you know that?
A. Because we tested it afterwards. We inflated the balloon to high pressure. There was no injury to the balloon and the balloons could have been used again.
Q. Dr. Low, just one last topic.
Were you in the court when Dr. Buller testified about how successful Cordis' Palmaz/Schatz, BX Velocity and Cipher stents were?
A. Yes.
Q. Okay. In your opinion, why was the Palmaz/Schatz stent commercially successful?
A. Well, it was commercially successful because it was the first -- the Palmaz/Schatz was the first coronary stent that was approved by the FDA for use in patients with blocked arteries. In other words, if you had a blockage and you didn't respond to medication and you could have bypass surgery or you could have balloon angioplasty, these patients then had the option of having a stent.
Now, when you do balloon angioplasty, most of the time it works fine. But, as we've learned, about 40 percent of the time, within six to 12 months, the artery gets narrowed again. And the reason it gets narrowed is because when it heals, it shrinks. Okay? It's an elastic healing and shrinkage.

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So with the stent, they showed from the Stress and Benestent trial that if you put a stent in, the stent holds the artery open. It's called scaffolding. It's providing support so that when it heals, it can't possibly shrink, because there's radial force. It's in a lattice pattern and it holds the artery open. So it can't shrink when it heels. But the price you pay is that when you put a metal object in, more growth factors are released and there's more scar tissue on the inside.
So if you look at the scar tissue after angioplasty and after a stent, the stent has more scar tissue that narrows the lumen, but because you've made it so much bigger with the stent than you could with the balloon, that gain is still more than you would have with balloon angioplasty, and that's why there's about a 10-percent difference in the Stress and Benestent trials between the balloon group and the stent group.
10 percent less of the patients got recurrent blockage. Now, how much is recurrent blockage? Well, the definition is that if you've got an artery that's this big, when you narrow that artery 50 percent in diameter, which is in cross-section 75 percent cross-sectional area narrowing, that's when you get impairment of blood flow.

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So in one of the studies, there was an average of 84 percent blockage. When they first took the pictures. After the stent was put in, there was a residual 34 percent blockage, something like that.
But even with that residual blockage, channel is more than 50 percent open and the patients do fine.
So that's how stenting works.
Q. Is the -- was the Palmaz/Schatz stent -- sorry. Was any of the success of the Palmaz/Schatz stent due to the fact that it was flexible enough to be delivered into coronary arteries?
A. Right. The Palmaz stent was never used for the heart because it was too rigid and it wouldn't bend. And as you can see, arteries to the heart are not only crooked and bent, but is constantly moving and contracting as opposed to arteries to the legs, to the kidneys, the shoulders and arms. They're big blood vessels and they're much larger and they're much straighter. But the heart arteries are curved.
So it took the modification of Dr. Richard Schatz, who's a cardiologist, as opposed to Dr. Palmaz, who's a radiologist, it takes a cardiologist to put things into the heart.
So Dr. Shatz made the modification by taking two short segments of Palmaz stents and putting in an

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articulation. A 1-millimeter piece of metal in between to make it so that it would flex at that one point. But when you do that, what you do is you give up the scaffolding. So at that gap, there's nothing to hold the tissue and support it against the wall and maintain that large channel.
And, in fact, that gap is where blockage can return more commonly than inside the stented segment because there's nothing holding it open.
In fact, they had a classification specifically for gap stenosis because of that gap. So if you're lucky and everything is held against the wall, you're fine, but if it turns out that plaque is -- the largest portion is right opposite the connector, then you've got a lot of tissue that's prolapsing through and you don't get a good result. If you see that, you have to go back in and put another stent in to cover that gap.
So the Palmaz/Schatz stent was very flexible and -- but it was only in the middle. The two ends were rigid and the whole length is only 15 millimeters, about three-quarters of an inch.
Now, in the United States, when that stent was introduced, the stent wasn't very securely mounted on the balloon, and it wasn't very deliverable because of the rigidity.

Exhibit M

United States Court of Appeals

FOR THE FEDERAL CIRCUIT

CORDIS CORPORATION,

Plaintiff-Cross Appellant,

—v.—

MEDTRONIC AVE, INC.,

Defendant-Appellant,

—and—

BOSTON SCIENTIFIC CORPORATION and BOSTON SCIENTIFIC SCIMED, INC.
(formerly known as Scimed Life Systems, Inc.),

Defendants-Appellants.

(*Caption continued on inside cover*)

APPEALS FROM THE UNITED STATES DISTRICT COURT FOR
THE DISTRICT OF DELAWARE IN CONSOLIDATED CASES 97-CV-550, 97-CV-700 AND 98-CV-19,
JUDGE SUE L. ROBINSON.

BRIEF FOR PLAINTIFF-CROSS APPELLANT/DEFENDANTS-APPELLEES/ DEFENDANTS-CROSS APPELLANTS

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December 22, 2006

MEDTRONIC AVE, INC.,

Plaintiff-Appellant,

—v.—

CORDIS CORPORATION, JOHNSON AND JOHNSON,
and EXPANDABLE GRAFTS PARTNERSHIP,

Defendants-Appellees.

BOSTON SCIENTIFIC CORPORATION and BOSTON SCIENTIFIC SCIMED, INC.
(formerly known as Scimed Life Systems, Inc.),

Plaintiffs-Appellants,

—v.—

ETHICON, INC., CORDIS CORPORATION,
and JOHNSON & JOHNSON INTERVENTIONAL SYSTEMS CO.,

Defendants-Cross Appellants.

enough to serve the inventor's purposes.'" A2048, quoting *Bausch & Lomb*, 796 F.2d at 450. Cordis then stated that a "clear purpose" of Dr. Palmaz's invention is providing a device "that is smooth enough that it can be intraluminally delivered from a remote location to a desired location without the risk of damaging the body passageway." A2049.

Cordis told the PTO that Ersek is not "smooth" in this sense. As Dr. Andros stated in his declaration, "[a]ny attempt to intraluminally deliver the [Ersek] fixation sleeve could result in shredding of the walls of the body passageway." A2079. For this reason, "[n]o responsible physician would consider intraluminally delivering … Ersek" and doing so "would present a clear risk to the patient." *Id.* As Dr. Andros explained, Ersek's outer surface accordingly is "not 'smooth', as that term is understood by those skilled in the art …." *Id.*; *see* A2077-79.

These statements are not a disclaimer of the relevant structure in the NIR. The NIR's surface – like the surface of the claimed stent of Dr. Palmaz's invention and unlike the surface of the Ersek fixation device – unquestionably is smooth enough for intraluminal delivery. BSC instructs doctors to deliver the NIR intraluminally. A26149-50.

Rather than disclaiming the NIR, Cordis cited it to the PTO as an example of a device with a "smooth surface." Cordis provided the Examiner with

a copy of the *Handbook of Coronary Stents* and directed the Examiner to page 134 for "examples of the meaning and common understanding of the term 'smooth surface.'" A2048. That page shows a photograph of the NIR stent and describes its "smooth surface" (A2132):

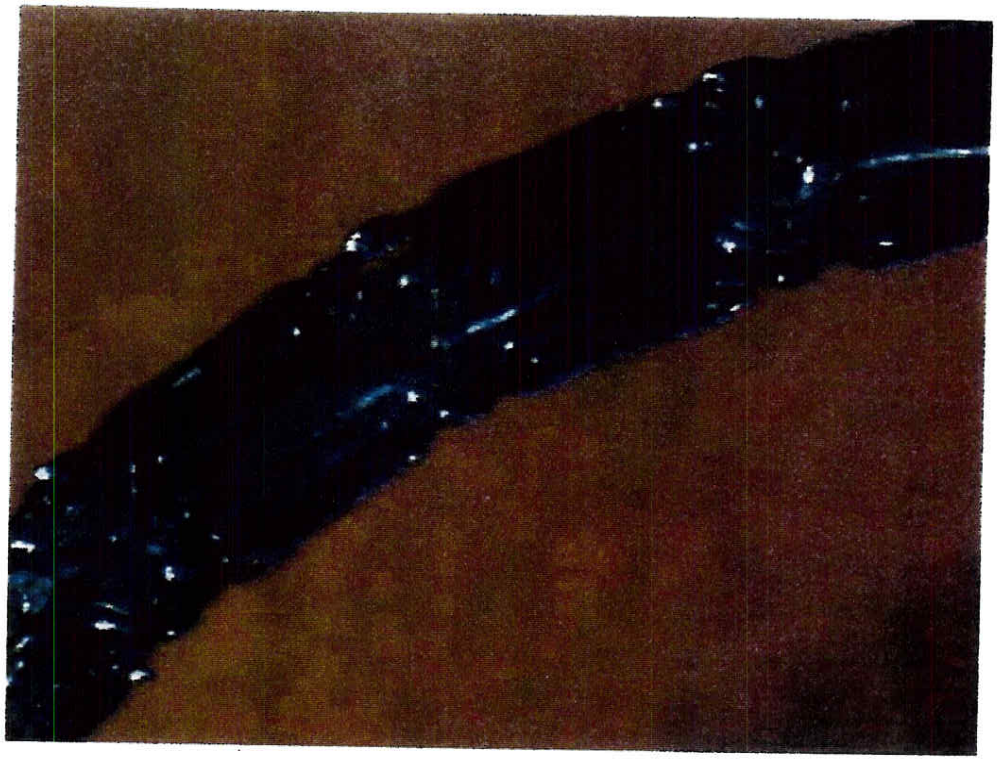


Figure 14.2: *The crimped NIR stent, showing a low profile of less than 1.0 mm and a smooth surface with no internal flare out points at the outside of a curved section. Notice also the difference between the slightly open struts of Figure 14.1 and the tightly crimped struts at this figure.*

Cordis's identification of the NIR as having a "smooth surface" is the antithesis of a surrender of coverage for the NIR.

Indeed, although the district court adopted a structural definition of "smooth surface," A369, the correct construction based on the intrinsic evidence

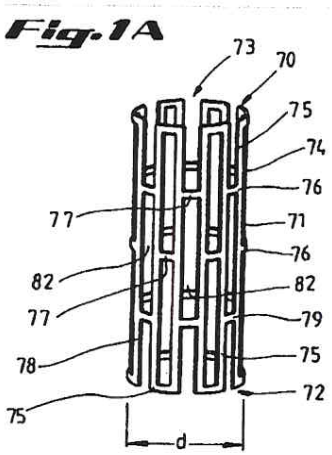
was the functional definition that Cordis used in its comments to the PTO. *See Medrad, Inc. v. MRI Devices Corp.*, 401 F.3d 1313, 1319 (Fed. Cir. 2005) (intrinsic evidence may make it "proper to consider the functions of an invention in seeking to determine the meaning of particular claim language"); *Honeywell, Inc. v. Victor Co. of Japan*, 298 F.3d 1317, 1324 (Fed. Cir. 2002) (file history statements can be "relevant in indicating the meaning that the inventor ascribed to the term"). Cordis advocated this functional definition in the district court, A9390-94, and may rely on it here as an alternative grounds for affirmance.[4] Under that (correct) construction, there is no need to address any equivalents issue as to smooth. It is undisputed that the NIR is smooth enough for intraluminal delivery and BSC instructs doctors to deliver it intraluminally. A26149-50. It thus literally infringes.

(b) In Distinguishing Ersek As Lacking a "Wall Surface" "Comparable" to that of the Fig. 1A Embodiment, Cordis Did Not Disclaim the NIR's Equivalent Structure

Cordis also relied on the bridge portions and sharp outwardly projecting edges of the Ersek device in arguing that Ersek lacks a structure "comparable" to the "wall surface" shown in Fig. 1A of the '762 patent. Once again, Cordis distinguished Ersek without a clear and unmistakable disclaimer of coverage for the NIR.

[4] *Resonate, Inc. v. Alteon Websystems, Inc.*, 338 F.3d 1360, 1368 (Fed. Cir. 2003) (an appellee may "present any legitimate argument in support of the judgment below, even if the argument was rejected or ignored by the trial court").

Cordis told the PTO that Ersek's "twisted, inclined strands … and bridge portions" do "not provide a 'surface' that is 'disposed between the first and second ends' of a tubular member as is recited in claims 13 and 24." A2050. Cordis stated "with particular reference to Fig. 1A" that "the connecting members and elongate members that collectively form the tubular member 71 [in the '762 patent] have an outer surface that is disposed in a common cylindrical plane." *Id.* This was just another way of describing the outer wall surface of the structure recited in the claim, *i.e.*, a "tubular member" (or tube) with a "substantially uniform thickness" and a "smooth surface."



Cordis then told the PTO that Ersek lacks a "comparable" wall surface. *Id.* The description of the Ersek device as lacking a structure "comparable" to a "wall surface" "disposed in a common cylindrical plane" was consistent with the file history comments distinguishing the saw-tooth configuration shown in Fig. 5 of the Ersek patent. *See AVE I*, 339 F.3d at 1361-62. This comment did not disclaim – let alone, clearly and unmistakably disclaim – other devices that *do* have a "comparable" wall surface.

Reading the prosecution history "as a whole," *Bayer*, 212 F.3d at 1252, Cordis's comments embrace, rather than disclaim, stents whose wall surfaces

POINT III

CORDIS' CROSS-APPEAL AGAINST BSC: THE DISTRICT COURT ERRED IN RULING THAT CLAIM 44 IS INVALID

The district court held that claim 44 is invalid under § 305, on the theory that it was filed "solely" for a supposedly impermissible purpose, *i.e.*, to cover competitors' products. A305. This ruling makes validity depend on something that is utterly irrelevant – the patentee's subjective motivation for wanting new claims. It treats a desire to cover competitors' products as an impermissible motivation, when the Supreme Court has described the right to exclude competitors as the essence of the patent grant. *Dawson Chem. Co. v. Rohm & Hass, Inc.*, 448 U.S. 176, 215 (1980).

The decision holding claim 44 invalid is at odds with the patent statute and case law. The file history shows that claim 44 was filed in response to an obviousness rejection, to distinguish the cited art. For claims (like claim 44) that are narrower than the original claims, that is all that is necessary under § 305.

A. Facts Concerning Cordis' Cross-Appeal

The initial Office Action during the '762 reexamination included an obviousness rejection based on the Ersek, Lazarus and Kononov references that Cordis had cited in the request for reexamination. A2010-24. Cordis then filed an Amendment "[r]esponsive to the Office Action." A2034. The Amendment

included arguments and added new claims 44-59, A2038-41, which Cordis described (accurately) as "narrower in scope than the original claims …." A2042.

New claim 44 is a method claim that generally follows the language of original claim 1, but has added limitations requiring: (1) delivery of the stent by "percutaneous catheterization," (2) to a "passageway of a coronary artery having an area of stenosis," (3) on a catheter that has "an inflatable balloon portion," (4) "without surgically exposing" the area to be treated, and (5) "controllably" expanding the stent at the desired location. A2038.

Cordis relied on these added limitations in arguing that: (1) it would be unsafe to deliver the Ersek fixation device "percutaneously," A2078-79; (2) Ersek does not teach use of a device in a coronary artery having an area of stenosis, A2044; (3) Ersek's sharp projecting edges could puncture a balloon, A2058; (4) Ersek and Kononov do not teach the use of a device in minimally invasive procedures, *i.e.*, without surgically exposing the area to be treated, A2044, A2056, A2075-76; and (5) Ersek, Lazarus and Kononov do not teach "controlled expansion." A2061.

B. Proceedings in District Court on Claim 44 Validity

At trial in 2000, BSC asserted that claim 44 was filed for a purpose that supposedly is "improper" under § 305 – "to [cover] the defendant's product …." A4422/BSC'00-Tr.2484:1-11 (BSC's closing argument). The district court

submitted that theory to the jury over Cordis's objection, A4431/BSC'00-Tr.2522:22-2523:8, and the jury accepted it.

Subsequently, the district court recognized that validity under § 305 is a "question for the court and not the jury." A302-03. It accordingly treated the verdict on claim 44 validity as an "advisory" verdict, *id.*, which is "not binding," *Wilson v. Prasse*, 463 F.2d 109, 116 (3d Cir. 1972), and does not deserve deference. *Ragin v. Harry Macklowe Real Estate Co.*, 6 F.3d 898, 907 (2d Cir. 1993).

The file history, discussed above, shows that claim 44 was filed to overcome an obviousness rejection. However, the district court seized on the statement in the file history that claims 44-59 are "narrower in scope than the original claims, and *provide specific protection for aspects of the disclosed invention which have been incorporated into competitive products and methods*." A2042 (emphasis added). Based on this statement, the district court concluded that claim 44 was filed "**solely** to cover competitors' stents." A305 (emphasis added). It then stated that a desire to cover competitors' products is "not … a permissible reason [for filing a new claim] under § 305," and ruled that claim 44 is invalid. *Id.*